K073593

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JAN 29 2009

Deltex Medical Limited
Terminus Road
Chichester
United Kingdom, PO19 8TX
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DELTEX MEDICAL

510(k) Summary
as required by 21 CFR 807.92

Owner's Name

Deltex Medical Ltd

Address:

Terminus Road
Chichester
West Sussex
PO19 8TX
United Kingdom

Telephone Number:	001 44 1243 523174
Fax Number:	001 44 1243 532534
Contact Person:	Lawrence Brookfield Regulatory Affairs Manager

Date

This Summary was prepared on November 12, 2007

Classification name:

Extravascular blood flow probe

The FDA has classified: "Extravascular blood flow probe" in 21 CFR 870.2120 as a Class II medical device with Product Code DPT

Common/Usual Name:

probe, blood-flow, extravascular

Proprietary Name:

Deltex Medical Ltd I_2n Series Doppler Probe
where n identifies the variant (S, P and C)

Establishment Registration Number:

The device will be manufactured by:

Deltex Medical Ltd
Terminus Road
Chichester
West Sussex
PO19 8TX
United Kingdom
Establishment Registration Number 9680933

and sterilized by:

Sterigenics UK, Ltd
Cotes Park Estate
Somercotes
Derbyshire DE55 4NJ
United Kingdom
Establishment Registration Number 3002807091

Substantial Equivalence:

The Deltex Medical Ltd I_2n Series Doppler Probe is substantially equivalent in design, use and materials to the:

Deltex Medical Ltd DP240 Hour Doppler Probe – K052989

and like the DP240 probe is for use with the Deltex Medical CardioQ system 9051-7005 - K031706

The Deltex Medical Ltd I_2n Series Doppler Probe is made of the same materials as the Deltex Medical Ltd DP240 Hour Doppler Probe (K052989). The significant differences are that the tip cover (boot) is made of non-pigmented rather than the white material, that is, the white pigment has been removed from the material formulation; and the pitch of the spring increased to improve flexibility for easy of insertion and comfort.

The Deltex Medical Ltd I_2n Series Doppler Probe is intended for the same use as the DP240 probe was cleared for in K052989: oral or nasal use in anaesthetized or sedated patients:

"... The DP240 is designed to operate in a clinical setting in which the patients are under general anesthesia or are sedated in the intensive care unit. The DP240 can be placed into the esophagus via oral or nasal insertion in adults." abstract from K052989 indications for use statement.

However the I_2n Series Doppler Probe has a "spring" which has been modified to reduce resistance to insertion; this makes it particularly suitable for nasal use in conscious and sedated patients.

The Deltex Medical Ltd I_2n Series Doppler Probe is manufactured by the same processes as the Deltex Medical Ltd DP240 Hour Doppler Probe (K052989).

The Deltex Medical Ltd I_2n Series Doppler Probe is sterilized under the same conditions as the Deltex Medical Ltd DP240 Hour Doppler Probe (K052989).

The Deltex Medical Ltd I_2n Series Doppler Probe, like the DP240 Hour Doppler Probe, is also substantially equivalent to the other Deltex Medical CardioQ Probe included in K031706 and the Arrow International, Inc, Hemosonic 100 Esophageal Probe, K972798.

Feature	Deltex Medical 'I_2n-series' Subject Device	Deltex Medical 'DP240' Predicate Device #1	Deltex Medical 'CardioQ Probe' Predicate Device #2	Arrow 'Hemosonic 100 Esophageal Probe' Predicate Device #3
FDA 510k number	This Submission	K052989	K031706	K972798
product name	I_2n-series	DP240 Probe	CardioQ Probe	Transesophageal Probe
common name	I_2n-series Doppler probe	240 Hour Doppler Probe	Esophageal Doppler Monitor Probe	Trans-esophageal Probe & Sterile Jacket
product number	9070 – 7015 9070 – 7016 9070 – 7017	9070- 7006	9050 - 7001	HSP – 02150 & HSS-02150
Device Description				
General description	Esophageal probe for measuring blood flow in the descending aorta Sterile For single use only	same	same	Trans-esophageal probe to provide PWD Doppler and M-mode measurement of aortic blood velocity and aortic diameter, respectively. Re-usable (with protective sheath)
Overall length	89 cm (35")	same	90 cm (35.5")	61 cm (24")
Shaft construction	Spring enclosed in silicone rubber	same	same	same
Shaft color	Clear (non-pigmented) shaft.	same	White (Pigmented)	Black

Feature	Deltex Medical 'I$_2$n-series' Subject Device	Deltex Medical 'DP240' Predicate Device #1	Deltex Medical 'CardioQ Probe' Predicate Device #2	Arrow 'Hemosonic 100 Esophageal Probe' Predicate Device #3
Shaft flexibility (N)	0.095	1.57	1.60	3.43
Main shaft diameter	14 FG (~4.8 mm)	same	17 FG (~ 5.5 mm)	20 FG (~7 mm)
Distal tip diameter	19FG (~6.3 mm)	same	same	20 FG (~7 mm)
Maximum Usage time (hours)	6, 24 or 72	Probe life (time-out): single use < 10 days/240 hours	Probe life (time-out): single use < 10 days/240 hours	indefinite (re-usable probe with single use sheath)
Main shaft wall thickness	0.03" (~0.7mm)	0.03" (~0.7mm)	0.04" (~1.0mm)	Not known
Marks in the shaft	The probe shaft has three depth markers at 35, 40 and 45 cm.	same	Same, but only two depth markers at 35 and 40 cm.	4 depth markers at 25, 30, 35 and 40 cm
Color of transducer head	"clear" (non-pigmented)	white (pigmented)	white (pigmented)	white
Color of the molded connector	"white" (pigmented)	white (pigmented)	white (pigmented)	The connection cable is covered with a black housing
Color of the shaft	"clear" (non-pigmented)	same	white (pigmented)	black
Connection to the monitor	non-reversible connector with ROM to identify probe type	same	same	Connection cable made of coaxial cables. The cable is symmetrical and each of its ends has the same male connector which locks by a simple click mechanism, without thread or bayonet. Only needs to align the red markers and gently push or pull to plug or unplug the connector to/from its base.
Doppler transducer / Central frequency	4MHz	same	same	5 MHz
Doppler transducer / Global maximum output	195 mW/cm^2	same	same	121 mW/cm^2
Doppler transducer / Mechanical index	0.039	same	same	0.089

Feature	Deltex Medical 'I_2n-series' Subject Device	Deltex Medical 'DP240' Predicate Device #1	Deltex Medical 'CardioQ Probe' Predicate Device #2	Arrow 'Hemosonic 100 Esophageal Probe' Predicate Device #3
Spring wire	0.030" (0.76 mm) diameter to BS5216 HS3, Pre-galvanized	same	same	Not known
Spring length	550mm (+/- 25 mm)	same	same	Not known
Spring internal diameter	1.80/2.00 mm	same	same	Not known
Spring external diameter	3.30/3.50 mm	same	same	Not known
Spring pitch	The spring has fewer turns per unit of length (it has a larger pitch than DP 240).	The spring has more turns per unit of length (it has a smaller pitch than I_2n).	as DP 240	Not known
ROM memory	This ROM memory is characteristic for the particular probe.	same	same	Not Applicable

Feature	Deltex Medical 'I$_2$n-series' Subject Device	Deltex Medical 'DP240' Predicate Device #1	Deltex Medical 'CardioQ Probe' Predicate Device #2	Arrow 'Hemosonic 100 Esophageal Probe' Predicate Device #3
Mode of operation	Esophageal probe transmits and receives 4 MHz Continuous Wave Doppler (CWD) ultrasound from the probe tip at a fixed angle to the descending aorta, by excitation of a piezo-electric transducer. The ultrasound is reflected by the red blood cells and is received by a separate transducer in the probe tip. Signals are returned via the Patient Interface Cable (PIC) to CardioQ Monitor. This permits to measure blood flow velocities in the descending thoracic aorta.	same	same	The principle of operation is based on the simultaneous, independent, real-time ultrasound measurements of aortic cross-section and blood velocity, to determine the instantaneous descending Aortic Blood Flow ("ABF"). The flowmeter uses a transesophageal probe with two ultrasonic transducers inserted into the patient's esophagus, either trans-orally or trans-nasally, and is externally orientable. One transducer is an M-mode echograph at 10 MHz which measures the CSA, and other is a pulsed Doppler transducer at 5 MHz which measures blood velocity. Aortic Blood Flow is a measurements of Cardiac Output.
Compatible Monitor	CardioQ monitor	same	same	HemoSonic 100 Monitor
Rx Status	Rx	same	same	same
Physicians Caution included in labeling	Yes	same	same	same
Indications for use				

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2009

Deltex Medical Ltd.
c/o Mr. Lawrence Brookfield
Regulatory Affairs Manager
Terminus Road
Chichester, West Sussex PO19 8TX
United Kingdom

Re: K073593
Trade/Device Name: I_2n Series Doppler Probe
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular Blood Flow Probe
Regulatory Class: Class II (Two)
Product Code: DPT
Dated: January 26, 2009
Received: January 28, 2009

Dear Mr. Brookfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073593

Device Name: I_2n Series Doppler Probe
Indications for Use:

The I_2 probe is for use with the Deltex Medical CardioQ for the monitoring of cardiac output and fluid status. The I_2 is only approved for oral or nasal placement into the esophagus of a single patient 16 years of age or older. The probe may be placed orally or nasally in sedated or anesthetized patients. The probe must be placed nasally in awake patients.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073593

(Posted November 13, 2003)